5 510(k) Summary

MAR 15 2012

Date Prepared: December 22, 2011

510(k) Submitter
Micromedics, Inc. 1270 Eagan Industrial Road, Suite 120 St. Paul, MN 55121-1385

Contact for Official Correspondence
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General Information			
Trade Name	Endoscopic Applicator	Common Name	Endoscopic Applicator
Classification Information	Endoscope and accessories per 21 CFR 876.1500 (Class II)	Product Code	GCJ
		Panel	General & Plastic Surgery
Predicate Devices	Endoscopic Applicator; Ethicon, Inc. (K051732) Endoscopic Applicator; Baxter Healthcare Corporation (K031882)		

Device Description

The Endoscopic Applicator is a sterile, single-use, disposable device intended for use in delivering hemostatic agents to bleeding surgical sites through a 5 mm (or larger) trocar. The Endoscopic Applicator is designed with a luer connector, which is used for connection to a syringe containing the hemostatic agent. The Endoscopic Applicator system consists of a cannula and stylet. The non-reflective cannula is a composite sheath constructed of PolyMed® (a high strength fiber with ester vinyl resin) with an Acrylonitrile Butadiene Styrene (ABS) over-molded luer lock. The stylet (obturator) consists of a PolyMed® composite rod, an ABS over-molded tip, and an ABS over-molded handle. The Endoscopic Applicator cannula and stylet are packaged in a double sterile barrier tray configuration and sterilized using ethylene oxide. Six individually sterile packaged applicators are contained in a shelf carton along with instructions for use.

Intended Use / Indications

The Endoscopic Applicator is intended for use in delivering hemostatic agents to bleeding surgical sites through a 5 mm or larger trocar.

Substantial Equivalence Comparison

The Endoscopic Applicator has substantially equivalent intended use/indications, principles of use and functional characteristics as the predicate Ethicon and Baxter endoscopic applicators. All three devices are intended for use in delivering hemostatic agents to bleeding surgical sites through a 5 mm or larger trocar. The subject and predicate device systems consist of a cannula and stylet. The cannula allows a common syringe containing hemostatic agent to be attached and permits delivery of the hemostatic agent to the intended bleeding site with the aid of the stylet. While all three devices allow access through a 5 mm trocar, they differ in length and biomaterials.

Summary of Non-Clinical Performance Data

The Endoscopic Applicator has been evaluated through design verification and biocompatibility testing. Biocompatibility testing performed in accordance with ISO 10993 - *Biological evaluation of medical devices, Part 1 – Evaluation and tests (2009)* show the device is considered safe for use for its intended biocontact. Non-clinical testing included the below tests and showed the test

articles met the pre-defined acceptance criteria, therefore demonstrating the mechanical integrity and suitability of the device for its intended use over the labeled shelf life.

- Volume test
- Flex test (stylet and cannula)
- Luer Lock tests (ISO 594-2)
- Hemostatic usage test
- Device leak test
- Pull / Torque tests (cannula)
- Pull / Bend tests (stylet)
- Cannula tissue compliance
- Shipping validation
- Shelf life evaluations

Substantial Equivalence Conclusion

The Endoscopic Applicator does not raise new questions of safety or effectiveness when compared to the predicate devices and is, therefore, substantially equivalent.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 15 2012

Micromedics, Inc.
% Intertek Testing Services
Ms. Paula Wilkerson
2307 E. aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K120608
Trade/Device Name: Endoscopic Applicator
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: February 28, 2012
Received: February 29, 2012

Dear Ms. Wilkerson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120608

Indications for Use

510(k) Number (if known): _____

Device Name: **Endoscopic Applicator**

Indications for Use:

The Endoscopic Applicator is intended for use in delivering hemostatic agents to bleeding surgical sites through a 5 mm or larger trocar.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mtm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120608